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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,422	07/03/2001	Rudolf Hauptmann	98,385-H	8840

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EXAMINER

O'HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	09/899,422	HAUPTMANN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 05 September 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

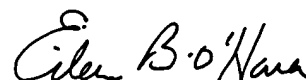
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 42.  
Claim(s) objected to: 46 and 47.  
Claim(s) rejected: 1, 23, 41, 45, 48 and 50-53.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**EILEEN B. O'HARA**  
**PRIMARY EXAMINER**

Continuation of 3. NOTE: new claims 54-62 would require new search and consideration and would require determining if there is support in the specification and whether the claims constitute new matter. .

Continuation of 11. does NOT place the application in condition for allowance because: Applicants traverse the rejection and submit that the TNF-BP of Wallach does not constitute a single species as a result of the processing of the N-terminus of human urinary TNF in vivo. Applicants discuss the evidence that the purification protocols described in the '953 patent and those described by Applicants are substantially similar, and the Applicants obtained a heterogeneous mixture of TNF-BP proteins from human urine, which resulted in a diffuse band which was due to the presence of a second polypeptide in a smaller amount, which is longer than TNF-BP at the end terminus. Amino acid sequence analysis revealed that only 80% of purified TNF-BP begins with ASP-41 of SEQ ID NO: 2, while a secondary sequence beginning with Leu-30 of SEQ ID NO: 2 was also detected (page 45), and therefore the TNF-BP purified from human urine is a mixture of at least two polypeptides whose N-terminus differs by 11 amino acids. Applicants submit that their purification protocol for human urinary TNF-BP d is substantially similar to that described by the inventors of the '953 patent, and that Applicants' purification protocol incorporates the purification steps of Wallach et al. as well as an additionally, highly purified purification step. Applicants point to column 10 in the related '701 patent, in which Wallach et al. conceded that his preparation was "substantially purified" and that the "initial yield" from protein micro-sequence analysis was over "40%, indicating that the major protein in the preparation (the 27 kDa band) is related to the resulting sequence". Applicants contend that recombinant TNF-BP is not produced via processing of its N-terminus and therefore will not contain contaminants beginning with Leu-30 of SEQ ID NO: 2. Applicants' arguments have been fully considered and are persuasive that the purified protein of Wallach et al. was a mixture of two TNF-BP's of different lengths. If Applicants could amend the claims to distinguish over the nucleic acids of Wallach et al., the rejection would be withdrawn. For example, claim 1 could be amended to recite that the polypeptide is a homogeneous polypeptide, which would not be anticipated by the heterogenous polypeptides of Wallach et al. . .



EILEEN B. O'HARA  
PRIMARY EXAMINER